UNIVERSAL HEALTH CARE
FOUNDATION OF CONNECTICUT

Testimony in Support of
House Bill 7123: An Act Limiting Changes To Health Insurers' Prescription Drug Formularies
Universal Health Care Foundation of Connecticut
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Universal Health Care Foundation of Connecticut thanks the Insurance and Real Estate Committee for the opportunity to submit testimony in support of House Bill 7123: An Act Limiting Changes To Health Insurers' Prescription Drug Formularies.

When an individual or small group chooses a health plan, part of what may inform their choice is the drug formulary. Prescription drug costs are a major concern for people[1], and likely a major consideration when they are choosing a health insurance plan.

But right now, on the individual and small group market, health insurers can sell one plan at open enrollment, and then make changes to the prescription drug formulary whenever they want. Prescription drugs costs are rising, but shifting those costs to consumers, *after they are locked into a health insurance plan*, is not a solution that helps anyone except the health insurer.

Even with notification of the changes to the prescription drug formulary, this practice is a "bait and switch" on the consumer, as consumers cannot change their plans until the next policy term. Despite any due diligence an individual or small employer does when shopping for a health insurance plan, it doesn't matter. An insurer can increase the cost-sharing of any medication at any time.

Consider extending this protection to the large group market, as well, as it is unclear whether this protection exists for large group health insurance plans.

Please note that Medicare Part D currently restricts mid-year formulary changes[2]:

> *Part D sponsors that change pharmacy benefit managers (PBMs) mid-year are required to continue the existing formulary. Decisions regarding formulary inclusion made by the previous PBM's P&T committee are binding on the assuming PBM. CMS will not approve negative formulary change requests for the purpose of aligning an existing formulary with that of a new PBM.*

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[1] See *Public Ranks Drug Costs and Sufficient Provider Networks Ahead of Affordable Care Act changes as Health Care Priorities for Next President and Congress to Address* (October 27, 2016) at http://kff.org/health-costs/press-release/public-ranks-drug-costs-and-sufficient-provider-networks-ahead-of-affordable-care-act-changes-as-health-care-priorities-for-next-president-and-congress-to-address/

[2] See Page 20 of Chapter 6 – Part D Drugs and Formulary Requirements of *Medicare Prescription Drug Benefit Manual* at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

In August 2016, the National Association of Insurance Commissioners Consumer Representatives released a report with recommendations for state policymakers on *Promoting Access to Affordable Prescription Drugs*[3]. One such recommendation is to restrict negative mid-year formulary changes, as was done in Texas (see attached excerpt from this report for more information). We'd like to highlight the following excerpt:

> *Mid-year formulary changes can have significant consequences for consumers. This is particularly true when plans remove a drug from a formulary altogether, move a drug to a higher level tier, otherwise increase cost-sharing for a drug, or impose more restrictive UM [utilization management] than what was originally in place when a consumer selected a plan. Because a change in drug coverage does not result in eligibility for a special enrollment period, many consumers who lose access to a drug through a mid-year formulary change will remain locked in a plan that does not meet their health needs. Some enrollees may receive continued access to their medication through the plan's exceptions process, but many enrollees are not aware of this option and not all exception requests are granted.*

There is no one easy solution for making health care more affordable. There are many players, many stakeholders, and many factors affecting our health. Affordable health care requires a coordinated approach with interconnected measures. This is one such measure, that ensures that health plan members are getting what they signed up for. Mid-year formulary changes that increase costs to consumers are not an acceptable solution. An insurer should not be allowed to change a health plan after a consumer is already enrolled.

We have to remember that health care affordability isn't just about lowering costs in the larger system – it's also about consumers getting the high-quality health care they need, at a price they can afford.

Universal Health Care Foundation of Connecticut's mission is to serve as a catalyst that engages residents and communities in shaping a democratic health system that provides universal access to quality, affordable health care and promotes health in Connecticut. We believe that health care is a fundamental right and that our work is part of a broader movement for social and economic justice.

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[3] See page 69 on mid-year formulary changes in full report, *Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders at:* http://healthyfuturega.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf

MID-YEAR FORMULARY CHANGES

Although access to comprehensive, accurate formularies is particularly important when consumers are shopping for coverage, formulary transparency remains important throughout the year since consumer health needs change over time. Despite the need for ongoing transparency and formulary stability, many plans change their formularies during the course of a plan year. Changes may be made as new drugs are added to the market or as utilization, pricing, and medical knowledge evolves over time.

Mid-year formulary changes can have significant consequences for consumers. This is particularly true when plans remove a drug from a formulary altogether, move a drug to a higher level tier, otherwise increase cost-sharing for a drug, or impose more restrictive UM than what was originally in place when a consumer selected a plan. Because a change in drug coverage does not result in eligibility for a special enrollment period, many consumers who lose access to a drug through a mid-year formulary change will remain locked in a plan that does not meet their health needs. Some enrollees may receive continued access to their medication through the plan's exceptions process, but many enrollees are not aware of this option and not all exception requests are granted.

Mid-year formulary changes are occurring in marketplace plans. According to an Avalere study of formularies in all 50 states and DC, nearly half of analyzed plans revised their formularies between October 2013 and September 2014.[219] Although the study did not find widespread negative mid-year changes in 2014, some plans dramatically reduced drug coverage for at least four classes of medication used to treat cancer, diabetes, multiple sclerosis, and asthma. Of the 41 plans that changed their formularies, 33 reduced drug coverage for at least one of these four classes of medication.[220] Six of these plans—18 percent—made significant drug coverage reductions, removing between 15 and 57 products during the plan year, and five of these plans saw drug coverage fall in at least one class by more than 15 percent.[221] Given these findings—and continued incentives for plans to limit adverse selection—regulators should remain vigilant in monitoring mid-year formulary changes.

Plans should have flexibility to make some mid-year formulary changes, such as adding newly approved drugs or biologics, removing drugs from a formulary after the FDA deems a drug unsafe, or eliminating UM requirements. These formulary changes have the potential to enhance consumer coverage, rather than detract from it, and should be allowed at any time.

However, plans should not be able to reduce the generosity of coverage after a consumer has enrolled. In particular, plans should be prohibited from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs. Such negative changes include:

- Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
- Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing; or
- Imposing more restrictive UM.

Although we strongly recommend that regulators prohibit mid-year formulary changes that reduce drug coverage, states that continue to allow this practice should adopt additional consumer protections. First, if a plan is removing a drug from its formulary, the plan should be required to continue covering that drug for all affected enrollees at the same cost-sharing level for the remainder of the year, a requirement adopted in Medicare Part D (Figure 22). Alternatively, states should allow a special enrollment period for enrollees who lose access to a needed drug due to a mid-year formulary change. Second, state insurance regulators should review and approve any mid-year formulary change that negatively affects enrollee access prior to the change being implemented to ensure that it does not discriminate against enrollees with significant health conditions or on other bases that are prohibited under the Affordable Care Act. In addition, insurers and their designees should be required to provide at least 60 days advance notice to enrollees, prescribers, and in-network pharmacies when making a mid-year formulary change. In particular, notices should include easy-to-understand information about the plan's drug exceptions processes and how a consumer can begin the process of securing an exception.

FIGURE 22:

Mid-Year Formulary Changes in Medicare Part D

Medicare has recognized the importance of formulary stability and imposes a number of limitations on mid-year formulary changes for drugs covered under Medicare Part D. Key components of the policy include the following:

- Part D sponsors can expand coverage at any time by adding drugs, reducing cost-sharing, or deleting UM.
- Part D sponsors must seek CMS approval for negative formulary changes, including removal of a drug from a formulary, higher cost-sharing, or new or more restrictive UM. Even if approved, affected enrollees are exempt from the change for the remainder of the plan year.
- Part D sponsors must provide 60 days advance written notice of an approved negative change to affected enrollees, pharmacies, and other stakeholders.

Source(s): Centers for Medicare and Medicaid Services, Chapter 6: Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual (Rev. 18, Jan. 2016).

State Action.

A number of states have prohibited or limited mid-year formulary changes or required insurers that do make such changes to notify consumers. Texas, for instance, enacted legislation to prohibit most mid-year formulary changes except at the time of coverage renewal (Figure 23). Even then, insurers must comply with additional requirements, such as notifying each affected enrollee and group sponsor and ensuring that the change is made uniformly across all identical or similar plans.

Nevada similarly prohibits most mid-year formulary changes but did so through the regulatory process. In 2015, the Nevada Division of Insurance promulgated regulations to prohibit insurers in the individual market from removing a drug from a formulary during the plan year except in limited circumstances.[222] Insurers are similarly prohibited from moving a drug to a tier with higher cost-sharing unless the insurer adds a generic alternative at the same tier or a lower tier during the plan year. The regulations allow insurers to add a drug to a formulary at any time.

FIGURE 23:

Texas Limits Mid-Year Formulary Changes

Individual and group health benefit plans in Texas have been prohibited from making mid-year formulary changes since January 1, 2012. Prohibited changes include:

- Removing a drug from a formulary;
- Adding a requirement that an enrollee receive prior authorization for a drug;
- Imposing or altering a quantity limit for a drug;
- Imposing a step-therapy restriction for a drug; and
- Moving a drug to a higher cost-sharing tier unless a generic alternative is available.

Under Texas law, these changes can only be made at renewal and must be adopted uniformly for all individuals or groups covered by identical or substantially identical plans. Insurers must also provide at least 60 days advance notice to state regulators and each affected enrollee before the change goes into effect.

Source(s): Tex. Ins. Code §§ 1369.0541, 1501.108

In promulgating these regulations, the Nevada Division of Insurance cited its authority to review and approve policy forms and develop standards on fair marketing and health plan availability. Since many states have comparable protections, other states could consider a similar regulatory approach to limiting mid-year formulary changes.

Other states have limited but not prohibited mid-year formulary changes. In New Mexico, plans cannot make most mid-year formulary changes within 120 days of any previous changes.[223] Such changes include removing a drug from a formulary, reclassifying a drug to a higher tier, imposing higher cost-sharing, or adopting or modifying certain UM restrictions. Insurers that make such changes have to notify affected enrollees at least 60 days in advance of the change.

Arkansas, Oklahoma, and Virginia have adopted similar notice requirements. In Arkansas, insurers and their designees must provide affected enrollees with at least 60 days advance written notice of a mid-year formulary change that increases an enrollee's financial responsibility.[224] Oklahoma imposes similar requirements but only when a drug is being removed from a formulary.[225] And Virginia requires insurers to provide at least 30 days advance written notice when moving a drug to a tier with higher cost-sharing requirements.[226] Virginia also requires insurers to establish a process for enrollees to obtain continued access to drugs that they have been receiving for at least six months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.[227] For more information on continuity of drug coverage, please see the section of this report on "Improving Access to Comprehensive Prescription Drug Coverage."

Federal Standards.

HHS has indicated that it is concerned about mid-year formulary changes, especially those that negatively affect enrollees.[228] Although HHS has not prohibited mid-year formulary changes for QHPs, federal regulators have noted that insurers "generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal" under guaranteed renewability requirements.[229]

In addition, HHS has required plans to provide a standard drug exceptions process, which allows an enrollee to request and potentially gain access to a medically necessary drug that is no longer covered under the formulary.[230] This presents an opportunity for some enrollees to receive continued access to their medication; however, not all enrollees are aware of this option and not all exception requests are granted. For more information on exceptions and appeals processes, please see the section of this report on "Improving Access to Comprehensive Prescription Drug Coverage."

Some mid-year formulary changes may implicate the Affordable Care Act's nondiscrimination protections. This is particularly true if changes are imposed in a way that disproportionately burdens individuals with chronic conditions. For more information on discriminatory benefit design, please see the section of this report on "Nondiscrimination in Formulary Design."

CONSUMER RECOMMENDATIONS

Consumer Recommendations on Mid-Year Formulary Changes

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Allow insurers and designees to add new products—including drugs, biologics, and biosimilars—at any time during the plan year.
- Prohibit insurers and their designees from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs, including:
    - Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
    - Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing; or
    - Imposing new or more restrictive UM requirements.

CONSUMER SUPPORT TOOLS

Consumer-facing support tools—such as formulary search tools or other "smart tools" with interactive features—can increase consumer knowledge, satisfaction with the decision process, and selection of a plan that aligns with the consumer's needs and preferences.[231] These tools can help fill significant gaps in consumer knowledge and highlight the need to consider certain plan elements, such as prescription drug coverage, to a consumer who might be unaware that benefits can vary dramatically by plan (Figure 24). Such tools may also be critical to attracting and retaining young people who expect to use consumer support tools to simplify their options and make a coverage decision.

Although decision support tools can be very valuable to consumers, the quality of these tools depends on the availability of meaningful and relevant content.[232] One consistent barrier to developing effective consumer support tools is a lack of relevant and standardized content. This barrier is particularly relevant to the development of drug-specific support tools since there are few standardized machine-readable formats or reporting requirements for formularies.[233]